

CHAPTER 4

HUMAN RESEARCH PROTOCOL SUBMISSIONS

PROTOCOL SUBMISSION PROCEDURE

Introduction

- 4.1** The approval process for human research protocol submissions is divided into two stages:
- a. Defence organisational clearance and endorsement, and
 - b. ethical approval.

Organisational clearance

4.2 Any research conducted within Defence or on Defence personnel must be of benefit to the Australian Defence Force (ADF). To determine this benefit, all human research protocol submissions require organisational endorsement before submission to the Australian Defence Human Research Ethics Committee (ADHREC). The pro forma in [annex A](#) is to be completed for all submissions. As indicated in [chapter 2—‘Organisational oversight of human research in defence’](#), it will be provided to the area of Defence with strategic responsibility for assessment of organisational and scientific merit before it is submitted to ADHREC. Where organisational oversight has already occurred at an appropriate level prior to submission, this should be clearly detailed in the protocol submission. All submissions are to be forwarded to the coordinating officer for human research in the Defence Health Services Division (DHSD) except where the Defence Science and Technology Organisation (DSTO) protocols have been internally assessed not to require ADHREC approval.

- 4.3** Prior to submission to ADHREC, the protocol should be reviewed by the appropriate strategic area in Defence responsible for the subject matter of the proposed research with respect to the following:
- a. the requirement for the research, particularly in response to an endorsed Defence research requirements document or research plan;
 - b. the applicability of the potential outcomes to Defence;
 - c. the appropriateness of the allocation of Defence resources (including human resources) required¹; and
 - d. the presence of sound scientific methodology^{2, 3}.

4.4 **Survey research.** *Human Research* which intends to use survey instruments to collect data from participants, whether such instruments are paper or computer-based, are subject to further Defence management requirements. However, note that most *Survey Research* will not also be *Human Research*.

4.5 Proposed *Survey Research* will be required to be reviewed by the Directorate of Strategic Personnel Planning and Research. Registration at an on-line database in accordance with the requirements of a Defence Instruction (*to be published*) is anticipated. Details of that registration must be included in the protocol application.

1 Reviewers should take particular note of issues such as coordination and duplication of research when assessing the appropriateness of the allocation of Defence resources.

2 Reviewers should also be cognisant of the experience and qualification of the researchers when assessing the appropriateness of methodology.

3 Assistance from appropriately qualified subject matter or technical experts may be required to undertake assessment for methodology. This may delay consideration of protocols.

Ethical approval

4.6 Once a protocol submission has been organisationally reviewed and endorsed, it will be provided to ADHREC for human research ethics consideration, as detailed in [chapter 3—‘Human research ethics’](#).

Modes of protocol submission

4.7 The preferred method of protocol submission is electronic, followed by a signed hard copy. If electronic submission cannot be achieved longer time frames for consideration of protocols may be required before approval can be provided. All submissions are to be sent to:

Human Research
CP2-7-067
Defence Health Service Division
Department of Defence
CANBERRA ACT 2600
Email: human.research@defence.gov.au

4.8 Although protocols are submitted by electronic mail, a hard copy is also required to conform with the National Health and Medical Research Council (NHMRC) requirement for ADHREC to keep signed original documents on file.

Format

4.9 Protocol submissions are to use the format in [annex A](#)⁴. Electronic versions of the form are available on the Defence Health Service website (Intranet and Internet) and by email request to the coordinating officer for human research in DHSD (human.research@defence.gov.au). In completing a submission the following points should be noted:

- a. **Project title.** A clear title to the project must be provided.
- b. **Endorsement by Defence Organisation.** Defence organisational endorsement seeks to establish if the research meets Defence organisational requirements. References to organisational plans and internal protocol review processes will be required.
- c. **Aims of the project.** The application should list the specific aims and potential significance of the project. The hypotheses or research questions should be clearly stated.
- d. **Lay description of the project.** The application should briefly describe the research in lay persons's terms.
- e. **Ethical implications of the project on humans.** Applications should identify the ethical implications of human experimentation involved in the proposal and explain how these issues will be addressed. If ethical clearance has already been received from another Human Research Ethics Committee (HREC), the approval letter from that HREC should be included in the submission to ADHREC. Outcomes from all HREC's that consider this protocol should be either attached to this protocol submission or forwarded to ADHREC immediately these are available.
- f. **Background, research plan and resource arrangements.** Applications should ensure that sufficient detail is provided for the Committee to understand and comment upon the proposal. Explanatory appendices are generally not to be included. Researchers should also indicate how their qualifications or experience are appropriate to the conduct of the submitted protocol.
- g. **Other research.** Applications must include full disclosure of all other ongoing research projects and grants held by the researchers.

⁴ This is an interim format form and future electronic formats will incorporate the most recent recommendations from the NHMRC.

- h. **Publications of the chief investigators.** Applications should list and number consecutively, the most recent papers accepted for publication in refereed or peer-reviewed journals or conferences (maximum one page per chief investigator). The listed information should be sufficient for copies of the publication to be accessed through standard procedures. Copies of these articles should not be included in submissions.
- i. **Budget.** If grants or other external funding have been obtained a budget detailing how the money will be spent must be included in submissions. All sources of sponsorship or funding, must be disclosed.

4.10 Further information on the detail required for completion of a submission is contained in annex A, [appendix 1](#).

Language

4.11 In accordance with the requirements of the *National Health and Medical Research Council Act 1992*, not all ADHREC members have a health or science background, therefore plain English is required. All technical terms and acronyms are to be explained in simple language, and technical jargon is to be avoided. **Information sheets and consent forms are to be in plain language that is easy to understand and phrased in a manner appropriate to the target study group.**

Information sheet and consent form

4.12 One of the primary ethical considerations in human research is informed consent. ADHREC requires that an easily understandable information sheet and consent form be provided to each prospective research participant. The study participant must sign the information/consent form and initial each page as having been read and understood by the participant. The participant is to be given a copy of the information/consent form to keep. A sample of an information/consent form is shown in [annex B](#). The form is to meet the following minimum requirements:

- a. The information section should be comprehensive and in plain understandable English or appropriate language (for example, Pidgin for Papua New Guinea volunteers) with risks sufficiently emphasised and quantified, where possible. The reasons for undertaking the research must be explained and if the research is being undertaken as part of a requirement to obtain qualifications this must be indicated.
- b. If an information/consent form exceeds one page, each page is to be numbered, eg 1 of 4, 2 of 4 etc.
- c. Each page of the information/consent forms must be marked with a version number and date.
- d. The statement is to be clearly made that volunteers may choose not to participate in the study or to withdraw from the study at any time with no detriment to their career or future medical care.
- e. Where protocols involve the taking of drugs dangerous to pregnant women (for example, some anti-malarials), a separate sentence, in bold, emphasising that pregnant women are not to volunteer for the study, is to be included.
- f. Information/consent forms must include a statement that a volunteer who is an ADF member of Defence employee is considered to be 'on duty' whilst participating in research.
- g. Any risks involved with the study are to be sufficiently emphasised and quantified on the information/consent form. The expression of the quantification should be positive not negative; for example: use the expression 'up to ...' as opposed to 'no more than ...' if required. Subjective descriptors such as 'minimal' or 'very low', are not to be used⁵.

5 Where a risk genuinely cannot be quantified, Investigators are to provide, and to personally endorse, a statement which compares the risk to another known quantity. For example, '... the risk of having an adverse cardiac event while undergoing this test cannot be quantified. However, I/We certify that to the best of my/our scientific knowledge the risk is less than 1/xxxx which is the risk of having an adverse cardiac event while undertaking exercise'.

- h. Statement of Privacy explaining that data are to be stored and handled in such a manner as to protect the anonymity of the participants.
- i. Where the study is a clinical trial as per the NHMRC definition, it will be stated that a nominal roll of study participants will be provided to ADHREC (or held on behalf of ADHREC) for the purpose of facilitating the tracing of participants should untoward circumstances develop in the future.
- j. Provide details on how to contact the investigators if necessary, including telephone numbers where appropriate. The following statement should always be included:

‘Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers in person, or you may prefer to contact the Australian Defence Human Research Ethics Committee at the following address:

Executive Secretary
Australian Defence Human Research Ethics Committee
CP2-7-130
Department of Defence
CANBERRA ACT 2600

Telephone: (02) 6266 3837
Facsimile: (02) 6266 3933
Email: ADHREC@defence.gov.au’

A copy of the proposed information/consent form is to be provided with the submission. Ethics clearance will not be provided without this.

ADMINISTRATIVE REQUIREMENTS

Intent to publish

4.13 One of the conditions of approval by ADHREC is that researchers acknowledge their intention to publish the results of their studies. This is to ensure that all results are made available, not only predicted or favourable results. Clearly, security issues must be considered and classified material cannot be published in open source media. There are other mechanisms to publish classified material through the Defence Publishing Service and the Defence Library Service.

Clearance of manuscripts for publication

4.14 Where manuscripts (including abstracts of verbal presentations) are prepared for publication, and the research has been conducted on Defence personnel, and/or at Defence establishments and/or the researcher is a Defence member, the manuscripts must be cleared through the relevant sponsoring authority (see [chapter 6—‘Manuscript review’](#)). This requirement does not apply to publications by DSTO staff or contractors that are approved for publication through DSTO’s authorised publication process. The Researchers Agreement ([paragraph 4.19](#)) will include an agreement to seek clearance from the relevant Defence sponsoring authority of all manuscripts consequent to the conduct of human research in Defence.

Archiving of researchers records

4.15 The Principal Investigator (first named Chief Investigator in submitted research protocol) is responsible for establishing procedures for the retention of data beyond the completion of the research project. ADHREC requires that all research data and other related records are to be held for a period of not less than five years, or in the case of clinical trials, not less than 15 years.

4.16 The records are to be stored in accordance with the [Privacy Act 1988](#) and other appropriate legislation.

Tracing of research participants

4.17 ADHREC has decided that it is part of the Committee's duty of care to volunteers to keep nominal rolls of all volunteers in clinical trials (as per the NHMRC definition). This is to enable tracing of study participants some time in the future should any problems arise that may be related to the research conducted. For clinical trials conducted by individuals, ADHREC requires that a nominal roll of study participants in clinical trials be provided by the investigators, after informed consent is obtained, for storage in the relevant protocol file. Where a clinical trial is conducted by a Defence research organisation (such as AMI or DSTO), that organisation is to certify that it will undertake the safe storage of the nominal roll for the requisite period. Sufficient detail is to be provided to enable tracing of each individual at a later date. This practice is consistent with current Occupational Health and Safety and Health Surveillance practices, is encouraged under the NHMRC National Statement, and has been endorsed by the Australian Health Ethics Committee (AHEC).

4.18 All ADHREC protocol files are secured in a locked filing cabinet and only the Secretariat has access to these files.

Researcher's Agreement

4.19 ADHREC requires that researchers agree to a number of conditions to secure ADHREC endorsement of their projects. An agreement is sent to the researcher when the protocol is approved to proceed. Researchers are requested to sign and return this agreement for lodgement with ADHREC. A sample Researcher's Agreement is shown in [annex C](#).

Guidelines for volunteers

4.20 ADHREC has developed a set of *Guidelines for Volunteers*, informing them of their rights and of ADHREC's role and responsibilities. Each study participant is to be given a copy of these guidelines to keep. The text of these guidelines is shown in [annex D](#).

Clinical pharmaceutical trials

4.21 When undertaking pharmaceutical trials, researchers may have to submit very detailed protocols to other HREC, funding bodies and pharmaceutical suppliers. However, ADHREC requires that researchers produce a full ADHREC submission in the format required in this chapter. It may be appropriate to attach the other detailed protocols as supporting documents.

Amendments to protocols

4.22 If an approved human research protocol is to be subsequently changed, **a written submission for clearance of the change must be made**. That change is not to be implemented until clearance from ADHREC has been received except where such change is related to an immediate safety issue for participants. The request should be in the form of a letter detailing the proposed change. Prior to seeking ADHREC clearance for amendments the agreement of the relevant area of Defence with strategic responsibility should be sought; the request to ADHREC should indicate that agreement has been obtained.

Submission time frames

4.23 ADHREC meetings are generally held seven to eight times a year. Meeting dates are promulgated at least two months beforehand. Meeting dates can be found on the Defence Health Service Intranet and Internet websites by following the links to *Research*.

4.24 Protocols are to be submitted (see [paragraph 4.7](#) for mode of submission) at least **25 working days** (five calendar weeks) prior to ADHREC meeting dates to allow for organisational review of the submission before forwarding to ADHREC members. **If organisational clearance cannot be obtained in this time submission to ADHREC will be delayed to a subsequent meeting**. Consequently, researchers are encouraged to submit protocol applications as early as possible, particularly if prior internal organisational clearance has not already been provided. **Researchers are reminded that neither organisational nor ethics clearance can be assured**.

Australian Defence Human Research Ethics Committee determinations

4.25 When ADHREC considers a research protocol, there may be one of four outcomes.

- a. **The protocol is approved outright.** This means that the protocol conformed to all ADHREC requirements and the Committee is satisfied that the research is ethical and can be conducted as detailed in the submission. When this occurs, the researcher will be sent a letter stating that the research has been approved, noting the ADHREC protocol number that has been assigned to it and enclosing a Researcher's Agreement for signature and return.
- b. **The protocol is approved conditionally.** Some minor amendments may need to be made to the information sheets or consent forms, or clarification of some aspect of the methodology may be required. In this case, the researcher will be sent a letter stating that the Committee has approved the project subject to some changes or clarification, the nature of which will be detailed in the letter. This enables protocol alterations to be made before commencing the research. The research is not to commence until these amendments have been forwarded to ADHREC and the researcher has received a responding letter stating that the protocol has been formally approved and enclosing a Researcher's Agreement.
- c. **The protocol is not approved and a resubmission is requested.** A letter will be sent to the researcher explaining why the study was not approved and detailing any amendments or issues that should be addressed in a resubmission. A resubmission will be subject to the time frame constraints outlined in [paragraph 4.26](#). Where the amendments required are substantial, researchers must note that ADHREC may insist on reconsidering the protocol resubmission during a subsequent formal meeting.
- d. **The protocol is not approved and a resubmission is not requested.** This will occur where a research proposal is judged to be fundamentally flawed on ethical grounds. A letter will be sent to the researcher explaining why the study was not approved. Any subsequent submission would be subject to the same process as the original submission, including the time frame constraints outlined in [paragraph 4.26](#).

Lapsed approval

4.26 If a research project has not commenced within 12 months of the date of ADHREC approval, approval lapses and the protocol must be resubmitted.

4.27 Ethical approval for all protocols is current for three years from the date of that approval being given. If a protocol will be used beyond this period further application for an extension submission is required.

Annexes:

- A. [Research Protocol Submission for scientific and ethical approval](#)
- B. [Information Sheet and Consent form](#)
- C. [Sample Researcher's Agreement](#)
- D. [Guidelines for volunteers](#)